WORKSHOP ON

RESEARCH FOR PREVENTION AND CONTROL OF HIGH BLOOD PRESSURE AND ASSOCIATED CARDIOVASCULAR RISK IN THE DEVELOPING COUNTRIES

(GENEVA, OCTOBER 9-12, 2001)

IC Health

www.ichealth.org

INITIATIVE FOR CARDIOVASCULAR HEALTH RESEARCH IN THE DEVELOPING COUNTRIES

ABOUT THE WORKSHOP

The Workshop on 'Research for Prevention and Control of High Blood Pressure (HBP) and Related Cardiovascular Risk in the Developing Countries' was organized by IC Health, during October 9-12, 2001 at Geneva. This Workshop was conducted in conjunction with Forum 5, the Annual Meeting of the Global Forum for Health Research (GFHR). It was sponsored by GFHR, World Heart Federation and Institute of Medicine, with technical support provided by the World Health Organization, Institute of International Health and Institut Universitaire de Medicine Sociale et Preventive (IUMSP). The Programme of the Workshop is appended. A total of 48 participants, of whom 30 were from the developing countries, participated in the workshop.

The Workshop reviewed the principles underlying the public health relevance of HBP control in the developing countries, the determinants and dimensions of CVD risk in individuals and populations and the strategies for reducing that risk with specific reference to HBP prevention and control. It identified the key principles and core design features of research studies intended to implement and evaluate interventions, for HBP and CVD risk reduction, directed at both the population level and at the level of individuals at high risk of CVD. It also recognized the value of a 'situational analysis' study (as proposed in Project P1 of *IC Health*), in providing a context specific framework for developing the interventions in different national/ regional settings.

The recommendations of t ...e partner institutions of *IC Health* as ...g country research network, to faci ...daptation, adoption and implementa ...ings with support from national and/c

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Background

Rationale

The expanding epidemic of cardiovascular diseases (CVD) in the developing countries will claim 18.4 million lives in 2020, according to the projections of the Global Burden of Disease Study (see figure I-II). Of these, 7.8 million deaths would occur in the age group of 30-69 years. High Blood Pressure (HBP) will be a contributor to many of these deaths, principally in the form of coronary heart disease, stroke and congestive heart failure. The risks associated with HBP (operating in a continuum across a wide range of systolic and diastolic blood pressures) and co-existing risk factors (with multiplicative risk contributing to a cumulative 'absolute' risk of CVD) have been clearly demonstrated in the observational studies. The potential benefits of reducing HBP (along with co-existing risk factors), will accrue from a combination of a 'population based strategy' to shift the distribution of blood pressure in the community, and a 'high risk strategy' for early detection and effective control of factors contributing to moderate or high CVD risk in individuals. These benefits have also been demonstrated in many clinical trials and some community intervention projects. *(The evidence is reviewed in the background document prepared for the Workshop and available on the website: www.ichealth.org).* Between 20%-30-% of the projected deaths in 2020 can be avoided by such an approach and many others can be deferred to an older age.

The initiation of national HBP control programmes in the developing countries will require a combination of research (which can inform policy) and capacity building (which can empower programmes). Research will be required to identify cost-effective and context-specific methods of applying existing knowledge as well as to bridge critical gaps in information by generating new knowledge. Capacity building will be required for enhancing the knowledge and skills of physician and non-physician healthcare providers (including community resources), and awareness in health system managers and policy makers, as relevant to the prevention and control of HBP and related CVD. Multi-sectoral coordination and networking will also need to be strengthened. The components of such a comprehensive programme are profiled in figures III-VII.

Figure I

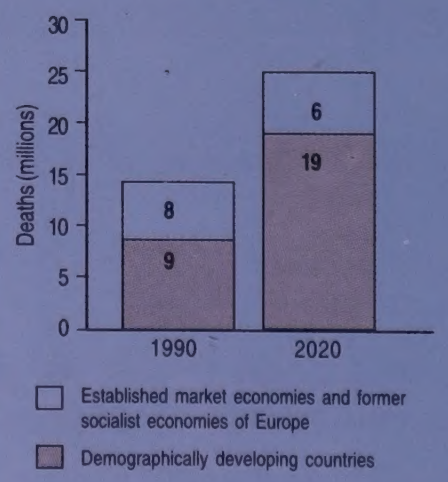
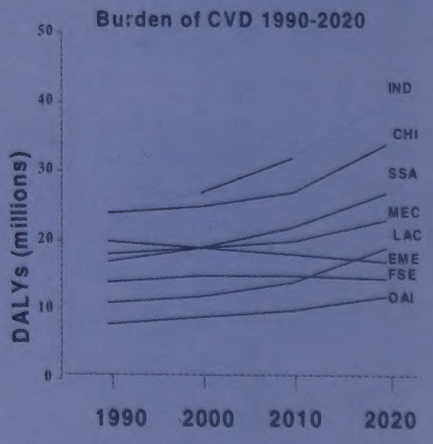


Figure: Cardiovascular deaths in lower and higher income countries: numbers reported in 1990 and projected for 2020 (Global Burden of Disease Project)

Figure II



Source: Murray CJ L., Lopez AD. The Global Burden of Disease. 1996.
IND=India; CH=China; SSA= Sub Saharan Africa; MEC=Middle Eastern Crescent; LAC=Latin America; EME=Established Market Economies; FSE=Former Socialist Economies; OAI=Other Asia and Islands

Figure III

PREVENTION AND CONTROL OF BLOOD PRESSURE AND ASSOCIATED RISKS

PREVENTION OF HIGH BLOOD PRESSURE AND ASSOCIATED RISKS *(POPULATION STRATEGY)*

- ❖ Community awareness (through health education)

+

- ❖ Enabling environment (through appropriate policies)

To promote

- Healthy Diet
  Salt reduction / substitution; decreased consumption of fat; increased consumption of fruits and vegetables
- Increased physical activity
- Decreased alcohol intake
- Maintenance of ideal body-weight
- Culturally appropriate stress management techniques

EARLY DETECTION OF PERSONS AT RISK OF BLOOD PRESSURE RELATED CVD

STEP I

- ❖ Opportunistic screening for high blood pressure and other risk factors for CVD including
  - Overweight
  - Central obesity
  - Tobacco habit
  - History of diabetes / CVD
  - Family history for CVD
  - Age, gender

STEP II

- ❖ Targeted screening for persons at moderate and high risk for CVD, as assessed at Step I
- ❖ Biochemical tests for Diabetes / dyslipedemia
- ❖ Clinical and investigative evaluation for CVD

COST-EFFECTIVE MANAGEMENT (PRIMARY PREVENTION)

Risk stratification employing standard and modeled risk assessment algorithms

↓

Management based on Risk Assessment

- Lifestyle modification
- Pharmacotherapy
- Acute care

MANAGEMENT ALGORITHMS

SECONDARY PREVENTION OF BLOOD PRESSURE RELATED CVD AND DISABILITY LIMATION

Evidence based, context-specific, resource-sensitive guidelines for

- Myocardial infarction
- Stroke/TIA
- Congestive heart failure

INTEGRATION INTO HEALTH CARE DELIVERY

- Community participation
- Healthcare provider training
- Referral Linkages
- Optimisation of healthcare delivery tools

Figure IV

INTERVENTIONS FOR PRIMARY PREVENTION OF CVD
Risk Detection + Risk Reduction in Individuals

EDUCATION → People / Professionals → **Self -Referral + Opportunistic Screening***

*HBP, Overweight, Tobacco, Physical Inactivity, Diet, Age, Gender, Personal/Family History

GUIDELINES
(Diagnostic Algorithms) → **Risk stratification (Step I) → Identify candidates for Targeted Screening****

**Diabetes, Dyslipidemia, Assessment for CVD

GUIDELINES
(Management Algorithms) → **Risk Stratification (Step II) → Appropriate Therapy**

Lifestyle Measures ± Drugs

Figure V

CAPACITY ASSESSMENT

COMMUNITY

- Health beliefs, attitudes, practices
- Access to information
- Networking within community
- Partnership with external agencies
- Access to health care – promotive, preventive and therapeutic
- Availability, affordability and acceptability of healthcare

HEALTHCARE PROVIDERS

- Attitude towards CVD
- Practice patterns of CVD risk identification, stratification and management
- Training, skills, time spent in context of CVD
- Access to, and acceptability of current guidelines
- Preventive practices
- Community networking

HEALTHCARE ADMINISTRATORS

- Currently operational programmes: content, resource, outreach
- Numbers, skills and training of health care providers
- Resources for essential care
  - Community health education
  - Essential drugs
  - Equipment
  - Patient education
  - Development of local guidelines
  - Referral linkage, and follow-up services
  - Surveillance system for CVD

POLICY & FRAMEWORK

- Tobacco control
- Food nutrition
- Education
- Drug production pricing, and supply
- Resource allocation
- Urban planning
- Healthcare financing
- Media
- Health NGOs

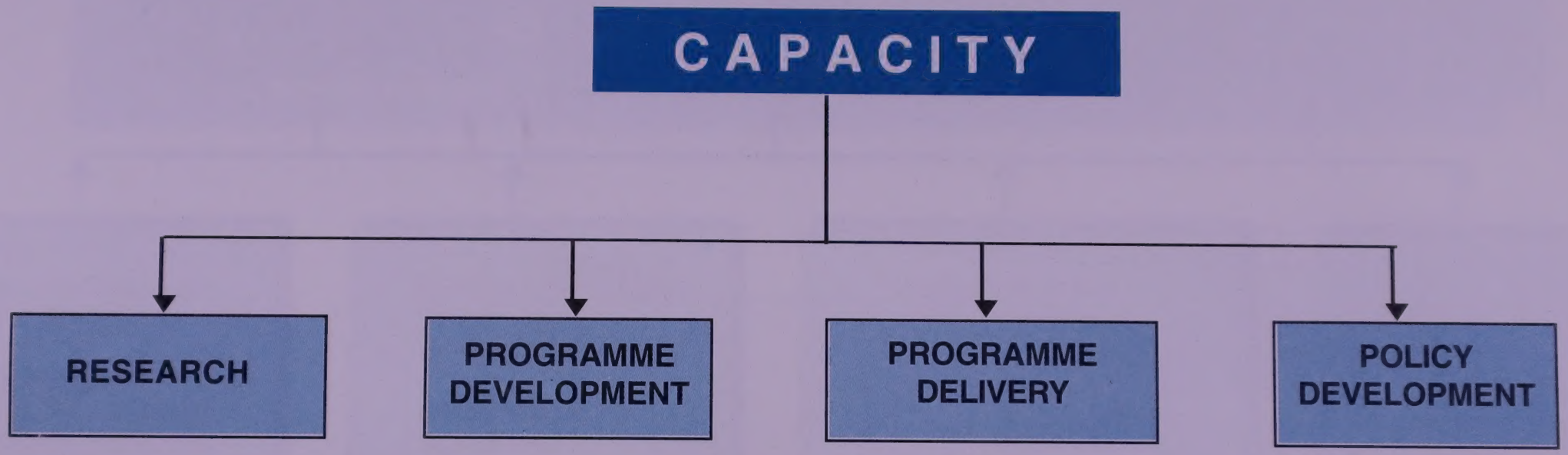
Quantitative information on healthcare inflastructure

Qualitative information on training and skills of healthcare personnel and perceptions of various stakeholders with regards to capacity for CVD control

Qualitative information on barriers and opportunities for community participation in CVD control programme

SITUATIONAL ANALYSIS

Figure VI



- ❖ Identification of optimal methods to appl yexisting knowledge effectively in regional context
- ❖ Generation of valid information where there are critical gaps in knowledge.
  For implementation of CVD prevention and control programme

- ❖ Consultative planning
- ❖ Optimization of health administration at various levels
- ❖ Integration of expert inputs to develop evidence -based context- specific and resource sensitive interventions for CVD control

- ❖ Dissemination and diffusion of programme instruments into healthcare systems.
- ❖ Programmes* directed at enhancement of knowledge and skills in —
  - Non-physician healthcare providers
  - Physician healthcare providers
  - Health system Managers
  - Community

** Detailed in Figure VII*

- ❖ Informed advocacy
- ❖ Multi-sectoral coordination
- ❖ Integration into the existing delivery systems
- ❖ Integration of efforts of all agencies with a stake in health.

Figure VII

CAPACITY BUILDING

PROGRAMME DELIVERY

Programmes directed at enhancement of knowledge and skills through

Training of non-physician health-care workers in

1. Health education and primary/ primordial prevention
2. Blood pressure measurement and preliminary risk assessment
3. Referral skills
4. Basic life-saving acute care

Training of physician healthcare providers in

1. Risk detection, stratification, and cost-effective management
2. Primary and secondary prevention strategies
3. Disability limitation
4. Cost-effective chronic care
5. Life-saving acute care skills
6. Programme advocacy
7. Building of partnership with other agencies

Training of health system managers in

1. Integration of project delivery into healthcare infrastructure
2. Multi-sectoral coordination
3. Monitoring and evaluation

Community training for

1. Health promotion
2. Self-referral
3. Self care
4. Family care

Principles of CVD Risk

The workshop recognized that cardiovascular risk in individuals is determined by risk factors which are distributed across populations and is influenced by the following principles.

Principle of Continuous Risk

Risk operates in a continuum and not across arbitrary thresholds. Risk reduction benefits across the entire range of distribution of risk factors.

Principle of Population-wide Risk

Majority of coronary/stroke events arise in a population from the middle of the distribution (of a risk factor) than from its high end.

Principle of Multiplicative Risk

Co-existence of risk factors leads to interactive risk which is multiplicative.

Principle of Comprehensive (Absolute) Cardiovascular Risk

The absolute risk of a major CVD event (CHD/ Stroke) is dependent on the overall risk profile contributed by co-existent risk factors operating in a continuum.

Atherosclerotic vascular diseases are multi-factorial in origin. Multiple risk factors coexist in variable combinations in different individuals (depending on diet, ethnicity, hereditary influences etc.). This clustering of risk factors interacts in a multiplicative fashion to enhance the risk of CVD. Thus the absolute risk of a major vascular event is dependent on the overall risk profile contributed by co-existent risk factors operating in a continuum. In most populations, the majority of CVD events arise from the individuals with modest elevations of many risk factors than in individuals with marked elevation of a single risk factor.

Strategies for Public Health Action to Reduce Risk

It is justified, from both a public health and a clinical perspective, that developing countries should focus their efforts towards the lowering of blood pressure and the prevention of blood-pressure-related diseases in both 'hypertensive' and 'nonhypertensive' persons. If reduction in blood pressure were to reduce the risk of blood-pressure-related disease in persons without hypertension, as much as it does in persons with hypertension, then the absolute benefits of even moderate population wide reductions in blood pressure would be substantial. Recent studies in East Asia suggest that a reduction of just 3% in average blood-pressure levels in such populations (for e.g., by sustained reductions in dietary sodium), would reduce the incidence of CVD almost as much as that would be achieved by antihypertensive therapy targeted to all hypertensive patients. This has important implications for future strategies to curb the epidemic of CVD. Preventive lifestyle interventions would assume much greater importance as these would be instrumental in tackling the risk factors in the population as a whole.

At the same time, there are many individuals who are at a high risk of future vascular events due to high blood pressure, with or without coexisting risk factors. Many of them are unaware of their risk, several are not on therapy of any kind and a large number are inadequately controlled for their risk despite therapy (*Please see the background paper on www.ichealth.org for data on awareness, therapy, and control status of HBP in the developing countries).* Risk factors of CVD often cluster together in such individuals and amplify the risk associated with HBP. Strategies to efficiently detect such individuals, in primary health care settings and to manage them effectively with evidence based, context-specific and resource-sensitive interventions (geared toward clinical management as well as health system strengthening) are, therefore, urgently required.

Both of these strategies ('population based' and 'high risk') are not mutually exclusive but are synergistically complementary. A comprehensive public health response to HBP and associated CVD risk must incorporate both of these approaches and integrate them into primary health care.

'Hypertension' (HBP) Control Programme as the Launching Pad for a CVD Control Programme

A hypertension control programme is ideally suited as an initiator of an integrated CVD (or even NCD) control programme in the developing countries for the following reasons.

- Hypertension is a risk factor for both coronary heart disease and stroke and operates as a major cause of CVD in all developing countries, despite varied levels of health transition.

- Hypertension (HBP) and tobacco exposure are both major risk factors for CVD and find a place in the top ten risk factors in the Global Burden of Disease study. While tobacco cessation efforts have been launched at a war footing by many international organizations, notably WHO, there are no such integrated efforts for the control of HBP.

- Large proportions of both men and women in the developing countries are exposed to this risk factor (unlike tobacco where women are, as yet, relatively less exposed). Thus the benefits would be manifest in both the sexes.

- The programme would have a 'clinical' appeal to both the health-care providers, and the community, eliciting stronger motivation.

- The goals are early measurable (in terms of proportions of population who are aware, treated & controlled)

- The impact on the above mentioned variables can be measured in a short time frame (5 years)

- As the blood pressure distribution in most developing countries is still to the left of that in developed countries, it provides us with sufficient time 'window' to act upon.

- It provides a natural coalition of various categories of health care providers (nurses; multipurpose health workers; general practitioners; internists; cardiologists, nephrologists, neurologists, obstetricians, ophthalmologists; nutritionists; stress therapists and exercise programme managers) all of whom have a role to play in the detection or management of hypertension and its sequelae in their routine work.

- The concept of 'comprehensive cardiovascular risk reduction' as a part of hypertension management makes it possible to incorporate strategies aimed at modifying other CVD risk factors (tobacco, high blood lipids, diabetes, obesity). This is so because comprehensive hypertension management would include modifications in diet, addictions, physical activity, stress etc, which are known to affect the other cardiovascular risk factors as well.

- Hypertension control has been shown to be even more effective than blood sugar control in reducing mortality in persons with diabetes. Thus in populations with rising rates of diabetes, such as India, this programme would be especially beneficial.

- Hypertension control programmes are unlikely to encounter organized resistance from vested interests (such as tobacco trade)

- The present level of scientific knowledge related to the benefits of lowering blood pressure and the availability of effective interventions makes it possible to initiate the programme in every community.

Issues in Research

The issues for research (situational analysis + evaluation of interventions) were identified to be:

A. What is the population profile of High Blood-Pressure (HBP), its determinants and associated risks?

   i) Prevalence of HBP in developing country populations (age, gender, rural-urban specific estimates)

   ii) Magnitude of HBP related disorders

   iii) Population distribution of risk factors contributing to HBP (e.g. obesity, salt consumption etc.)

   iv) Population distribution of risk factors contributing to CVD, along with HBP (associated risk factors)

B. What is the prevalence of other cardiovascular risk factors and what is their significance in context of a specific population?

C. What are the knowledge, attitudes and practice patterns in the community with reference to high blood pressure?

D. What are the knowledge, attitudes and practice patterns in the health-care providers with reference to HBP?

E. Are measures like modifications in diet, exercise, attainment of ideal body weight, control of central obesity, moderation of alcohol intake and relaxation therapy being practiced? What are their relative priorities in the context of specific populations?

F. Can HBP associated risk of CVD be predicted through a clinical risk score, for management decision making at primary health care level in developing countries?

G. What is the cost-effectiveness of different approaches available for high blood pressure detection and management, which can be utilised in a CVD control programme?

Aims and Objectives of proposed Research Projects

The overall objective of the proposed research project is to develop, implement and evaluate community based interventions, in varied developing country settings of primary health care, intended to reduce the risks of cardiovascular diseases (CVD) related to high blood pressure (HBP) and associated risk factors.

The enabling objectives are:

A. Research objectives pertaining to assessment of current capacity, in various developing country settings, for initiating a community based intervention programme for the prevention and control of HBP and associated cardiovascular risks (Situational Analysis).

B. Research objectives related to: the evaluation of the cost-effectiveness of interventions which (i) enhance the ability of the community to adopt healthy behaviours relevant to the prevention of HBP and (ii) enhance the ability of health care providers to detect and control HBP and associated cardiovascular risks more effectively than at present; and assessment of the further impact of these interventions on the risk of HBP and associated cardiovascular risks in the community.

C. Research objectives related to the evaluation of the feasibility and cost-effectiveness of capacity building programmes at various levels, which meet the gaps identified in research component A and are an integral component of interventions listed in research component B.

Specific Research Objectives

We aim to conduct quantitative and qualitative research, within selected communities from diverse developing country populations (selected from six developing regions as described in the Global Burden of Disease Study), to meet specific objectives, which relate to the above enabling objectives.

Research should be conducted, through survey methodology, to identify

1. Current knowledge, attitudes and practices (KAP) in the community related to
   - Risk behaviours influencing blood pressure
   - Risks associated with high blood pressure
   - Benefits of interventions for risk reduction

2. Access to, and affordability of health care services for detection and management of HBP and associated diseases.

3. Current KAP among primary health care providers, of different categories, related to
   - Magnitude of HBP and related health problems in the community
   - Risk behaviours leading to the development of HBP
   - Risks associated with HBP
   - Associated risk factors, which contribute to the absolute risk of CVD along with HBP
   - Benefits of interventions, which can prevent HBP
   - Benefits of interventions that can reduce the risks associated with HBP
   - Current guidelines for detection and management of HBP, including risk stratification, and
   - Screening practices for evaluating individuals for risks associated with HBP.

4. Estimates of the prevalence of HBP in the population group (stratified for age, gender, urban-rural residence); proportion of persons

at moderate to high risk of CVD; proportions of persons with HBP who are aware, on treatment and adequately controlled.

B. Research should also aim to:

5. Develop and validate cost-effective clinical algorithms for risk stratification based on easily measurable clinical indicators (direct and surrogate markers of risk), in comparison to conventional risk stratification algorithms which incorporate clinical and laboratory indices (estimates of diagnostic accuracy; misclassification rates; comparative cost-effectiveness), in the specific context of each developing country population.

6. Develop and evaluate the cost-effectiveness of educational interventions, for modifying KAP in the community, as relevant to the prevention and control of HBP and associated risk factors.

7. Develop and evaluate the cost-effectiveness of educational interventions, for modifying KAP of primary healthcare providers, as relevant to the prevention and control of HBP and associated risk factors.

8. Evaluate the impact of these educational interventions on
   - Distribution of BP(systolic and diastolic) in the population ;
   - Proportion of hypertensive persons in the population who are aware of their BP and risk status, are on therapy and are adequately controlled;
   - Proportion of persons at moderate or high risk of CVD (at baseline & post-intervention)

9. Model estimates of potential benefits of these changes in B.P and CVD risk on the CVD events in the population and evaluate the modeled cost-effectiveness of the programme.

C. Research should evaluate the feasibility and cost-effectiveness of capacity building programmes intended to:

10. To enhance the capacity among ***physician health care providers***, at the level of primary and secondary health care, to detect, classify and manage HBP and associated risk factors of CVD.

11. To enhance the capacity among ***non-physician healthcare providers***, at the level of primary health care, to detect HBP and associated risk factors and contribute to their management, in accordance with physician-provided guidelines.

12. To enhance the capacity among ***health system managers***, to integrate programmes for prevention and control of HBP and related CVD into the primary and secondary health care infrastructure.

13. To enhance the capacity, among different components of the health care system, to develop and implement ***community education programmes*** intended to promote awareness and adoption of behaviour leading to reduced risk of HBP and CVD.

14. To enhance the capacity for ***multi-sectoral coordination*** and integrated delivery of healthcare services, with involvement of public, private and voluntary sectors.

15. To enhance the capacity for ***informed advocacy***, among health professionals and community groups, for policy change conducive to the creation of an enabling environment for prevention and control of HBP and CVD.

II. Key Issues and Recommendations Related to Research Design of Studies Evaluating The Impact of Interventions

II (a) *Workshop on population-based interventions*

The Workshop focused on the population based interventions intended to promote behavioral changes that will positively influence blood pressure distribution in the population.

KEY ISSUES

The working group identified the following as key issues in designing a research project to evaluate the effectiveness of interventions to alter population distributions of blood pressure.

- Any intervention package has to be appropriate to local culture and, therefore, will need to be defined at the national / regional level. However, key elements are likely to be common and should be considered for inclusion in each national project, even though operational details and relative priorities may differ.

- The intervention package will have multiple components. It would be difficult to disentangle the specific effects of each component in a population based study which does not have the discriminant ability of a factorial clinical trial. However, such a search for specific effects is unnecessary in a population based intervention where a combined 'lifestyle package' is likely to have health benefits beyond blood pressure lowering. When even clinical trials (e.g., the DASH trials and the Mediterranean diet trials) have identified the benefits of 'composite diets', a reductionist paradigm need not be a barrier to the administration and evaluation of a multi-component intervention at the population level.

- It would be desirable to have a 'comparison group' so that the effects of the intervention, independent of secular trends, can be assessed. While the limitations of community based trials in providing unbiased comparisons are well recognized, such a design has the advantage of studying interventions in real world conditions and addressing a wide range of risk across the population.

- The main issue for operational research would be to examine whether it is possible to lower mean blood pressure levels in the community, through a population based intervention that is intended to improve knowledge, motivation, skills and facilities for adopting or increasing behaviours that are known to lower blood pressure.

- Research will need to focus on outcomes (blood pressure distribution shifts) but process measures too will be important with respect to the level of implementation of the intended programme components.

- Qualitative research will have to be an important component of the project, since changes in beliefs and attitudes are best evaluated by qualitative methods. Even changes in behaviours and barriers to change are often better identified

by a combination of qualitative and quantitative research methods than by quantitative methods alone.

- Economic evaluation of the programme is also essential to determine the cost-effectiveness of the interventions in different developmental and health settings. The resources required for various levels of programme implementation must be well quantified and related to the indicators of impact.

DESIGN FEATURES

Research Question: "Will population based measures (incorporating community education as well as policy components) succeed in reducing mean blood pressure levels in a selected community, in contrast with a comparison community?"

Selection of Intervention Community: As appropriate to each country. The community should be a 'natural unit' of the population rather than a special group.

Selection of the Comparison Community: This should have similar socio-demographic characteristics and cultural patterns but should be geographically separated so as to remain insulated from the educational intervention. Wherever possible, the policy component of the intervention too should be restricted to the intervention community and not influence the comparison community. This may be possible by selecting the comparison community from a different province in the country, with a different administration but similar social cultural characteristics.

Baseline Survey: This should be conducted, over the same time period, in both intervention and comparison communities.

- Blood pressure
- Other Cardiovascular Risk Factors
- Knowledge and Attitudes of Community Groups
- Key Behaviours (Diet; Physical Activity; Tobacco and Alcohol)

These surveys should provide *disaggregated data* in age and gender specific groups and the overall population distribution of each variable.

VARIABLES TO BE STUDIED IN THE BASELINE SURVEY

By Questionnaire	Age: Gender; Personal history (of high blood pressure, diabetes, angina, myocardial infarction, transient ischaemic attacks, stroke, peripheral vascular disease, congestive heart failure); Family history (of heart attack, stroke or sudden death, in first degree relatives, occurring below the age of 60 years); History of exposure to smoking, other forms of tobacco and alcohol.
By Physical Measurement	Height; Weight; Waist Circumference; Blood Pressure (Systolic, Diastolic), Pulse Rate
By Blood Biochemistry	Fasting blood levels of Total Cholesterol, HDL Cholesterol, Triglycerides and Glucose

Intervention: Intervention should comprise of educational and policy components intended to influence key behaviours:

- Diet (↓ sodium intake; ↑ Fruit and vegetable intake;↓ Saturated and Trans Fats)
- Weight control
- Regular moderate physical activity
- Smoking (avoidance / cessation)
- Alcohol (moderation / cessation)

For each of these, the targets to be achieved should be quantified and conveyed in culturally appropriate recommendations:

BEHAVIOUR SHOULD BE INFLUENCED THROUGH	
ACTIVITIES	**AGENCIES**
Training	Local Government
Education	Health Care System
Social Environmental Engineering	NGOs (including health professional bodies)
Economic Incentives	Community Networks and Schools

The intervention should be a combination of *'top down'* policy interventions (eg; food supplies / manufacture, transport, price and tax measures) as well as *'bottom up'* community mobilisation (education, motivation and skill enhancement through health professionals, community networks, NGOs and schools).

End points

(a) Behaviours: diet; physical activity; smoking (tobacco); alcohol

(b) Risk Factor Levels: Blood Pressure Pulse Rate, BMI, Lipids, Glucose

(c) Events: Fatal and non-fatal CVD events; Total mortality.

Behaviours will be early end points, risk factors will be intermediate endpoints and CVD events will be late endpoints, during followup and sequential evaluation.

Evaluation methods

Baseline and followup surveys (of processes and outcomes involving behaviours and risk factor levels in the population) will need to be conducted in both intervention and comparison communities. Routine surveillance data will have to be utilised for evaluation of events, where available.

Time frame

The project would need to be conducted over 10 years, with study planning, preparation of instruments and training of research staff in year 1, a baseline survey completed by year 2, interventions commencing in year 3, repeat surveys in years 5 and 9 and analyses in year 10.

II (b) *Workshop on high-risk CVD prevention in primary health care settings*

The workshop discussed the Interventions aimed at identification and management of individuals at high risk of CVD due to HBP/Combination of CVD risk factors, through algorithm based risk reduction instruments.

The working group recommended that the research project in this area should be a randomised clinical trial, with community groups as units of allocation. The interventions should comprise of (a) educational and motivational programmes aimed at primary health care providers, intended to promote opportunistic screening for HBP and CVD risk factors, a stepwise approach to risk stratification and algorithm based management strategies to reduce CVD risk, (b) community education to promote awareness of HBP and associated CVD risks as well as benefits of lowering HBP in order to promote self-referral for evaluation by primary health care providers and (c) patient education programme to promote informed self care and improved adherence in persons detected to be at high risk of CVD and advised appropriate therapy.

The suggested model of such a study would include (a) ***randomisation*** of geographically defined communities to the 'intervention' and 'usual care' programmes of HBP detection and management; (b) ***baseline survey*** of practice patterns in primary care practice and community surveys to identify prevalence of HBP/high CVD risk individuals and assessment of awareness, treatment status and control status of individuals with HBP as well as community beliefs related to HBP and associated risks; (c) ***interventions*** directed at primary health care providers (to improve detection of HBP, CVD risk assessment and management, and informed patient participation in healthcare) and speified population groups (d) ***repeat surveys*** at the end of intervention to evaluate the impact of intervention and (e) economic evaluation of cost-effectiveness.

The sample size of the number of communities (to be recruited and randomised in the trial) would need to be determined, in each country, based on prior/ pilot study information on prevalence of individuals HBP and high risk of CVD and proportion of such persons who are currently managed appropriately (in accordance with accepted national/international guidelines) and anticipated impact of the intervention package in increasing the proportion of such well managed individuals. A model study design for such a project in India is provided overleaf.

Baseline Surveys

i) Surveys of the community

The survey would be designed to obtain information about the following factors—

a) Socioeconomic and demographic determinants of CVD risk
b) Clinical and biological risk factors for CVD
c) Knowledge, Attitudes and Practices (KAP) relating to HBP and associated risks, their prevention and control.

Specifically, information would be elicited for the various variables as stated in the Section II (a) by questionnaires, physical measurements and blood biochemistry.

ii) Surveys of health care providers and health services

The survey of health care providers will assess knowledge, attitudes and reported practices with regard to the control of blood pressure-related diseases and other cardiovascular conditions. All of those involved directly in patient care (doctors, nurses, and health workers) will be surveyed after selection through stratified random sampling of enumerated lists of that area. The survey will be conducted using a self-administered questionnaire as well as focus group discussions.

A clinical audit will assess retrospectively, from whatever medical records are available, the usual practices of health care providers with regard to the

MODEL DESIGN FOR A RANDOMISED TRIAL IN INDIA*

26 Communities each with Population > 20,000

Matched Random Allocation

13 intervention communities

13 control communities

Baseline Survey
- Consecutive high-risk individuals surveyed at healthcare facilities (n=200 in each community)
- Random sampling of the general population aged 25-79 years (n=1000 in each community)

Development of simple algorithms for prevention of cardiovascular diseases (HBP↓; CVD Risk↓)

Health Care Providers:
- Opportunistic screening
- Cost-effective prescriptions

+

Community:
- Increased awareness of CVD+ Self- referral of high- risk individuals
- Lifestyle modification

Control (two years)

Intervention (two years)

Follow-up Survey
- Identical to Baseline Survey

OUTCOMES

Primary: Change in proportion of high-risk individuals attending the healthcare facilities who are prescribed appropriate treatment (based on evidence based, context-specific algorithms)

Secondary: Change in knowledge, attitudes and practices related to cardiovascular diseases and their determinants in the community

*Developed by Institute for International Health and Scientific Secretariat of IC Health

identification of patients at moderate to high risk of cardiovascular disease, the management of chronic conditions (e.g. heart failure, cerebrovascular disease, coronary heart disease), institution of preventive therapies, as well as the management of acute cardiovascular events (e.g. stroke and myocardial infarction). Additionally, prospective audits of clinical practice will be conducted and the relevant resources available for use in each community will be documented (including access to sphygmomano-meters, laboratory services, electrocardiographs, hospital care and specialist services and treatments of proven efficacy).

A survey of health education practices in the community and its resources will also be performed. This will involve the retrospective documentation of health education and health promotion activities conducted within the past 12 months and as far as possible, those planned for the next 24 months. It will also assess resources available for such activities (including the availability of funds, materials, and health care personnel experienced in health education). This will be conducted through structured interviews with representatives of local, regional and national health authorities.

Interventions for community health education

The community health intervention will consist of a health promotion campaign that will primarily target adults and the elderly, although it will also include information relevant to younger age groups. The principal aims will be to improve the knowledge, attitudes and practices of individuals in the population, with regard to the causes, symptoms, prevention, and treatment of HBP and HBP related CVD. It is anticipated that the effects on knowledge, attitudes and practices will lead to changes in risk factor levels among individuals in the intervention population. A further aim will be to facilitate the self-identification and self-referral of individuals at moderate or high risk for cardiovascular complications/blood-pressure-related diseases (for e.g. a known diabetic, hypertensive smoker might become aware of the need to have his blood lipids measured). There will be a focus on blood pressure and the campaign will include information about the effects of blood pressure on cardiovascular risk and ways in which blood pressure can be reduced by lifestyle change (e.g. reduced salt intake, salt substitution, physical activity, attainment of ideal weight, avoidance of excess alcohol intake) as well as by drug therapy. Information about the health effects of tobacco will be included, as will information about smoking cessation. Other factors such as blood cholesterol, diabetes and obesity will be targeted where they are appropriate in the context of the population risk profile and the healthcare capacity of the region. A key component of the implementation of the health promotion campaign will be the involvement of the local media, with additional activities developed and conducted by health care providers, community groups, non-governmental health care organizations, educational authorities, and governmental agencies. The campaign will be developed on the basis of extensive local consultations with multiple stakeholder groups.

Interventions aimed at health care providers

The individual health component will be implemented principally though training and education programs targeting those involved with the care of persons seeking clinical care. The programme would involve healthcare workers at all levels with emphasis on non-physician health care workers (like nurses and community health workers) in rural areas and both physicians and non-physicians in the urban setting. This would be based partly on the cost-effective analysis of diagnostic algorithms, carried out as a part of the baseline survey. The individual health component will focus on the training of health care providers in the use of simple methods for the identification, classification, and management of those patients at moderate and high risk. Additionally, community workers and nurses would

be trained for measurement of blood pressure and anthropometric indices, imparting health education for lifestyle modification and would be provided with simple guidelines for identification and referral of patients at high risk for cardiovascular disease.

The educational programme will incorporate training elements on:

(a) Where to Screen

— Use 'Opportunistic Screening' methods at routine health care consultations in primary health care to detect individuals at high risk of CVD and requiring blood pressure lowering interventions to reduce that risk.

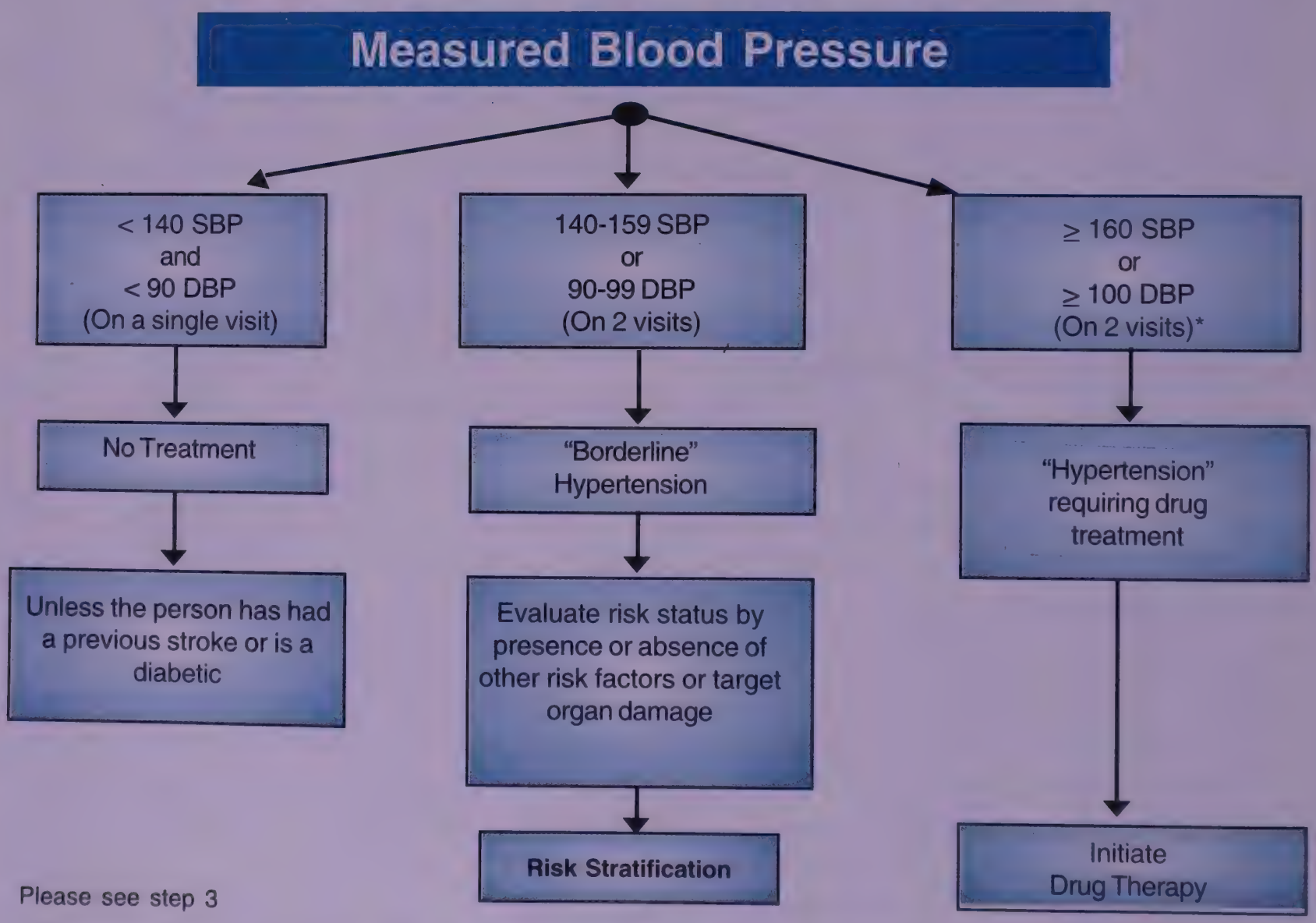
(b) Who to Screen

— Individuals who provide a past medical history of cardiovascular disease or hypertension
— Individuals ≥ 40 years of age
— Individuals 30-39 years of age, who have any one of the following risk factors:
  - diabetes mellitus
  - overweight (clinical judgment/measured BMI)
  - current smoker
  - family history of CVD under 60 years

(c) How to stratify CVD risk status to guide decisions related to blood pressure lowering interventions

Step 1: Risk stratification based on measured blood pressure

Individuals who are not already on blood pressure lowering medication, will be stratified according to BP levels measured during the baseline survey.

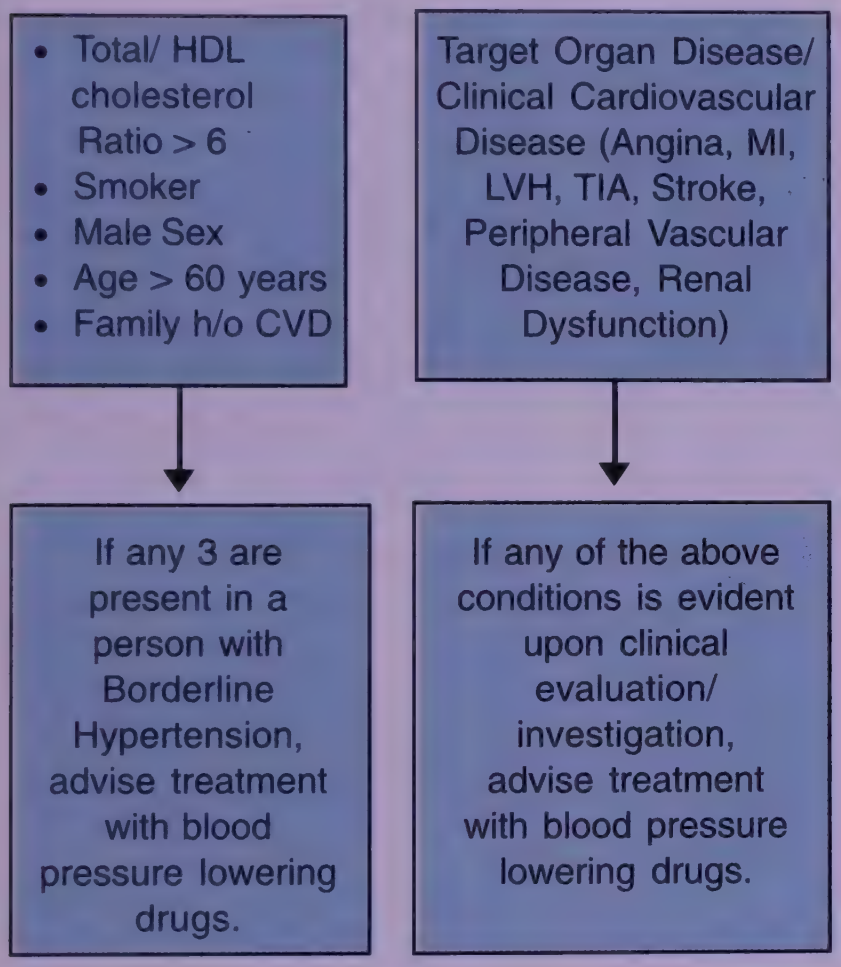


Please see step 3

* Persons with BP levels of SBP ≥ 180 or DBP ≥ 110 may be initiated on treatment if multiple measurements on the first visit (2 pairs of measurements, 30 mts. apart) record those levels.

Step 2: Risk stratification, based on other risk factors and target organ disease, in persons with 'borderline hypertension'

In persons with *'borderline hypertension'* (as defined in step 1), the presence of other cardiovascular risk factors or target organ disease should be utilized to identify individuals at a high risk of future CVD events and thereby requiring drug treatment for hypertension. All individuals with 'borderline hypertension' should receive advice regarding non-pharmacologic measures for BP reduction.



Step 3: Special Situations: Risk based intervention in persons with diabetes or previous stroke

In persons with diabetes, blood pressure levels need to be maintained below 130/85 mm. Hg (JNC VI, WHO-ISH Guidelines). Persons with diabetes are at a high risk of future CVD events, on par with persons with previously manifest coronary heart disease. Blood pressure lowering interventions in diabetic individuals are highly effective in reducing the risk of future CVD events (UKPDS). Vascular protection with an ACE inhibitor is also effective in reducing future CVD risk in diabetics (HOPE trial).

As such, persons detected to be diabetic during the baseline survey (fasting blood sugar ≥ 126 mg% or known diabetic) should be placed on blood pressure lowering drugs if their blood pressure levels are ≥ 130 mm. Hg SBP or ≥ 85 mm. Hg DBP.

Persons with a previous history of stroke will benefit from blood pressure lowering, across a wide range of blood pressures, through a reduced risk of future CVD (PROGRESS trial). It is, therefore, recommended that a person with a previous stroke should be placed on blood pressure lowering medication, irrespective of the baseline blood pressure.

(d) Treatment algorithms for individuals who require blood pressure lowering interventions (table below)

CO-DETERMINANTS	BORDERLINE HT SBP 140-159 or DBP 90-99	HYPERTENSION SBP ≥ 160 or DBP ≥ 100
Other Risk Factors 0 1 2	Non-Drug Methods For BP Lowering	Drug Therapy + Non-Drug Methods
Other Risk Factors ≥ 3	Drug Therapy + Non-Drug Methods	
Target Organ Damage/ Clinical Cardiovascular Disease/ Diabetes	Drug Therapy + Non-Drug Methods	

(e) Non-pharmacological measures to lower BP (site specific)

These should incorporate advice on:

- alcohol (reduction or cessation)
- salt and other sodium products (reduce intake)
- weight (reduction, if overweight)
- fruit and vegetables (increase intake)
- foods high in saturated fats/ trans-fats (reduce intake)
- smoking (cessation)
- exercise (increase physical activity)

(f) Drugs to lower BP (site specific)

Guiding principles for choice of drugs:

- Effective
- Inexpensive
- Once daily administration

To choose among:

- Thiazide, Beta-blocker, ACE inhibitor, Calcium Channel Blocker, Reserpine
- Use combinations, when needed, to achieve effective control with less side effects (frequently $\geq$ 2 drugs may be required).

(g) Target blood pressure

- Set to achieve SBP $<$ 140 and DBP $<$ 90
- If possible, seek to attain WHO-ISH goal of $<$ 130 SBP and $<$ 85 DBP

(h) Other treatment

- Use aspirin when indicated (pre-existing CVD; individuals over 50 years with 'controlled' BP levels of SBP $<$ 150 and DBP $<$ 90 mm. Hg)
- Use lipid lowering drugs, when indicated by blood lipid levels, for primary or secondary prevention of CHD

(I) Referral and followup

Guidelines for

- Referral to secondary care (non-response of BP to Rx; evaluation of CHD etc)
- Followup advice from secondary to primary care (monitoring; adherence; patient education etc)

(I) Patient and family education

- Training programmes for health care providers to enhance their skills in providing patient education and (where feasible) family education, to enhance their participation in care and promote long term adherence to agreed therapies.

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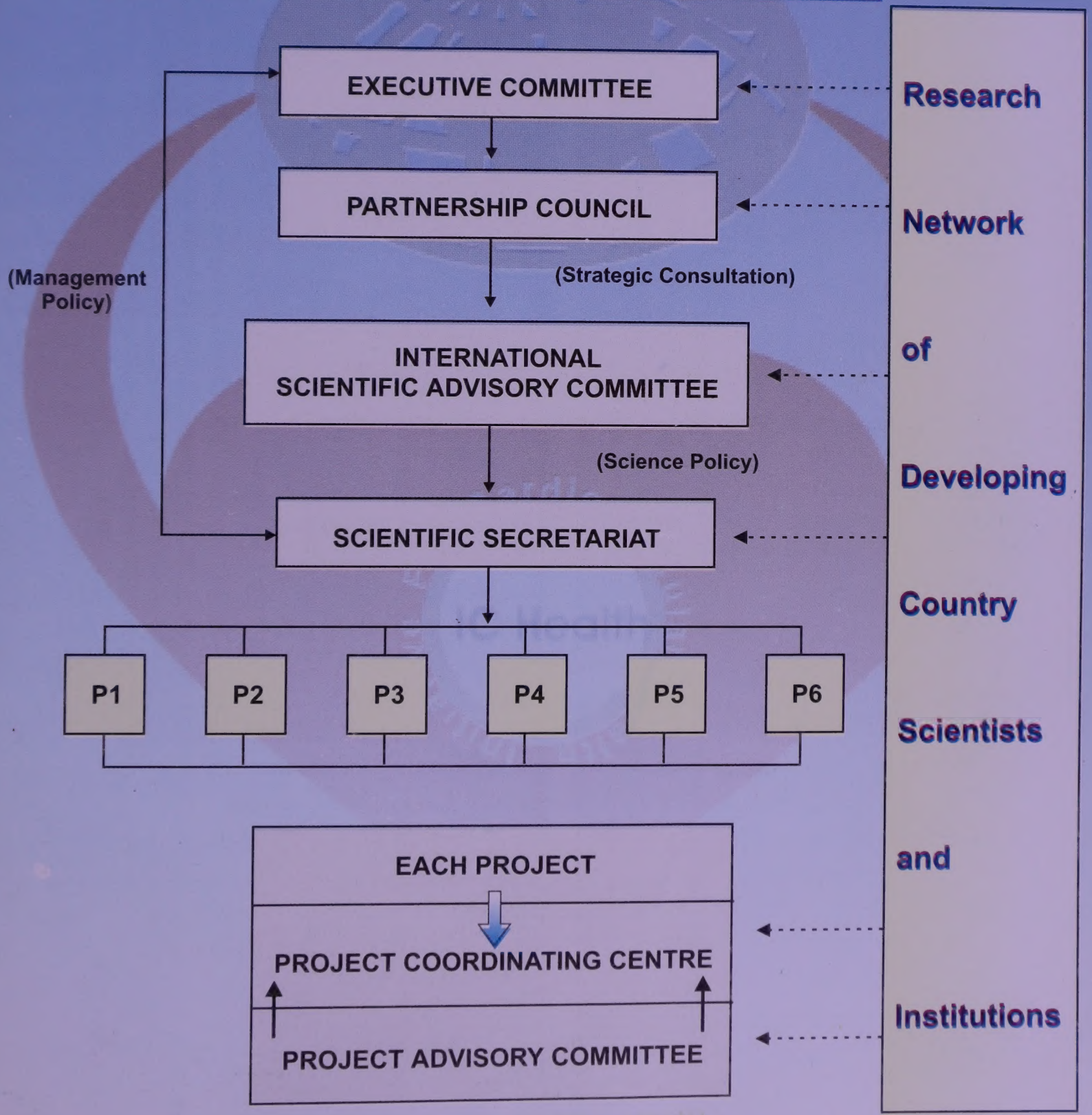
INITIATIVE FOR CARDIOVASCULAR HEALTH RESEARCH IN THE DEVELOPING COUNTRIES

Organization Flow Chart



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